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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,215	04/07/2005	Elias Castanas	P/567-129	1523

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,215	CASTANAS, ELIAS	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-21 and 28-47* is/are pending in the application.

4a) Of the above claim(s) *19-27,38-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-37,40,41 and 43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 19-21 and 28-47 remain pending.

Applicants election of Group 9 (claims 28-37, 40, 41, 43, drawn to a method wherein an antiandrogen is not used) is acknowledged. As previously acknowlwedged, the elected disease (to be treated) is prostate cancer. In addition, the elected conjugate is testosterone-3-(O-carboxymethyl oxime/HSA). Given that no "detectable label" has been identified, it is apparent that the elected conjugate is not detectably labeled.

Claims 28-37, 40, 41, 43-47 are examined in this Office action; claims 19-27, 38-40, 42 are withdrawn from consideration.

✧

Claims 28-37, 40, 41, 43-47 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites that the "composition is conjugated" with a protein. A composition, however, is not the same as a compound. A composition is a mixture of a single compound and one or more other compounds. Thus, it is unclear what is intended here. One interpretation is that the requirement for a composition that is "conjugated with a protein" could be met if one took a mixture of the steroid and a second compound and conjugated the mixture such that only the second compound became bonded to the protein. For example, one could take a mixture of a steroid and an amino acid, and conjugate that mixture to a protein, wherein the protein in question is albumin minus the N-terminal amino acid. The result would then be a mixture of albumin and the steroid; the requirement for a "conjugate" is then met because one compound within the composition did indeed form a conjugate with the albumin (minus the N-terminal amino acid). That is, by a semantic "sleight of hand", a conjugate according to claim 28 is really not a

conjugate, as this term would be understood by a peptide chemist. If applicants do not intend to convey such a possibility, then it is suggested that the claim be amended to require that the steroid is covalently bonded to the mammalian protein in question.

In claim 44, there is a relatively minor issue. The claim can be interpreted to mean that the composition is not actually administered to the patient. One of the following could be used:

A method of treating prostate cancer comprising administering to a patient in need thereof a composition comprising....

A method of treating prostate cancer comprising administering to a patient suffering therefrom a composition comprising....

A method of treating prostate cancer comprising administering to a patient afflicted therewith a composition comprising....

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 28-32, 34, 37, 40, 41, 43 are rejected under 35 U.S.C. §103 as being unpatentable over Larsen (USP 6740304) in view of Haugwitz (USP 5157049) or Chen (USP 5248796) or Stella (USP 4960790).

Larsen discloses immunoconjugates for treating cancer. The immunoconjugates comprise a radionuclide and folate. In addition, the immunoconjugates can also contain (col 3, line 22+; col 4, line 63) estrogen or testosterone. Larsen does not suggest combining the conjugates with taxol. Each of the secondary references discloses that taxol can be used to treat cancer. Thus, it would have been obvious to one of ordinary skill to combine the two agents for additive effects.

✧

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER